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09/982,091	10/17/2001	Akiko Kumagai	CIT1320-1	6755

7590

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/982,091

**Applicant(s)**

KUMAGAI ET AL.

**Examiner**

Daniel M. Sullivan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5, 7, 10-15, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 7, 10-15, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 18 April 2005 in reply to the Non-Final Office Action mailed 15 October 2004. Claims 5, 7-15 and 23-26 were considered in the 15 October Office Action. Claims 8, 9, 23 and 24 were canceled and claims 5, 7, 10, 11, 25 and 26 were amended in the 18 April Paper. Claims 5, 7, 10-15, 25 and 26 are pending and under consideration.

#### *Priority*

For reasons of record, claim 26, which is directed to a polynucleotide having a nucleotide sequence as set forth in SEQ ID NO: 3, does not find support in the prior provisional application. Therefore, the claim is afforded an effective filing date of 17 October 2001.

#### *Response to Amendment and Arguments*

Rejection of claims 8, 9, 23 and 24 is rendered moot by the cancellation thereof.

#### Claim Rejections - 35 USC § 112, first paragraph

Rejection of claims 5, 7, 10, 25 and 26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendments to the claims such that they are now directed to polynucleotides encoding or comprising the disclosed sequences.

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Claims 11-15 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In response to the *prima facie* case of record, Applicant has amended the claims such that they now depend from claim 7, which is now directed to a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2 or the nucleotide sequence as set forth in SEQ ID NO: 1. In the remarks, Applicant contends that the claimed nucleic acids are now directed to polynucleotides comprising the entire sequence set forth in the SEQ ID NOs recited in the claims. However, the vector of claims 11-15 is not limited to comprising the polynucleotide of claim 7. Instead the claim recites that the vector comprises “a polynucleotide of claim 7”. As such, the claim encompasses a vector comprising any sequences of two or more nucleotides within the scope of claim 7. Therefore, for the reasons set forth in the previous Office Action, the claims still encompass subject matter that is not described in the disclosure such that the skilled artisan would recognize Applicant was in possession of the full scope of what is presently claimed.

#### Claim Rejections - 35 USC § 102

Claims 11-15 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Goodearl *et al.* (June 1999) WO 99/28470.

In response to the *prima facie* case and arguments of record, Applicant has amended the claims such that they depend from claim 7. Applicant contends in the remarks that the amendment renders the art rejection moot. However, as discussed above, the vector of claims 11-15 is not limited to comprising the sequence of claim 7 but a sequence of claim 7. As described in the Office Action mailed 28 April 2004 (page 7), Goodearl *et al.* describes a recombinant

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expression vector comprising an isolated nucleic acid molecule that is identical to nucleotides 4715-4754 of SEQ ID NO: 1 according to the limitations of claims 11-13, a host cell comprising the vector according to the limitations of claim 14 and a method of producing a polypeptide according to the limitations of claim 15. For these reasons, the teachings of Goodearl *et al.* anticipate the instant claims.

Claim 26 **stands rejected** under 35 U.S.C. 102(e) as being anticipated by Schlegel *et al.* WO 01/60860 (previously made of record).

Applicant has amended the claim such that the claim is directed to a polynucleotide that consists of a polynucleotide having “the nucleotide sequence set forth in SEQ ID NO: 3 or a polynucleotide as set forth in nucleic acid residues 1-331, 799-903, 1232-1543, 2147-2486 or 2964-4756 of SEQ ID NO: 3”. In the remarks, Applicant contends that Schlegel *et al.* does not disclose a nucleic acid having the sequence set forth as SEQ ID NO: 3 because there are mismatches at positions 1963 and 2071 of the query sequence.

This argument is not deemed persuasive because the nucleic acid of Schlaegel *et al.* does have a polynucleotide as set forth in nucleic acid residues 1-331, 799-903, 1232-1543, 2147-2486 or 2964-4756 of SEQ ID NO: 3. Although the preamble of the claim recites that the polynucleotide “consists of” polynucleotides having the limitations recited in the body of the claim, the claim is construed as open to any polynucleotide comprising the fragments recited because the open transition “having”, recited in line 3, can be construed as referring to the fragments as well as to the full length SEQ ID NO: 3. Therefore, the broadest reasonable interpretation of what is claimed encompasses any polynucleotide comprising a fragment of SEQ

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ID NO: 3 recited in the claim, which nucleic acid is anticipated by the nucleic acid of Schlaegel *et al.*

***New Grounds for Rejection***

**Claim Rejections - 35 USC 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11-15, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 part (e) is indefinite in being directed to a degenerate variant of parts (a), (b), (c) or (d). As parts (a) and (b) encompass any polynucleotide encoding the amino acid sequence set forth as SEQ ID NO: 2, it is unclear how the degenerate variants of part (e) differ from what is claimed in parts (a) and (b). As the polynucleotide of part (c) presumably does not encode a functional polypeptide, it is unclear what is encompassed by a degenerate variant of the complementary sequence of part (b). Likewise, because there is no reading frame specified that would identify a particular polypeptide sequence encoded by the polynucleotide of part (d) with which to determine metes and bounds of degeneracy, it is unclear what is encompassed by a degenerate variant of claim 7, part (d).

Claims 11-15 and 25 are indefinite insofar as they depend from claim 7.

Claim 25 is further indefinite in depending from claim 7 and being directed to a polynucleotide encoding a polypeptide consisting of the amino acid sequence set forth as SEQ

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ID NO: 4. As the polynucleotide of claim 7 encodes the polypeptide of SEQ ID NO: 2, not SEQ ID NO: 4, there would seem to be no antecedent basis for a polynucleotide encoding a polypeptide consisting of the amino acid sequence set forth as SEQ ID NO: 4 in claim 7.

Finally, claim 26 is indefinite in depending from claim 9. As claim 9 has been canceled the metes and bounds claim 26 are now unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Goodearl *et al.* (*supra*).

Claim 10, part (b), is directed to an isolated polynucleotide comprising a polynucleotide complementary to a polynucleotide having the nucleic acid sequence set forth as SEQ ID NO: 5. In view of the use of the indefinite article in referring to the nucleic acid sequence, the claim can reasonably be construed as encompassing a polynucleotide complementary to any fragment (*i.e.*, any two contiguous nucleotides) of SEQ ID NO: 5.

Goodearl *et al.* discloses a nucleic acid sequence comprising the sequence 'GGCTT' (nucleotides 84-88 of SEQ ID NO: 4), which sequence is complementary to the first 5 nucleotides of SEQ ID NO:5. Thus, the nucleic acid of Goodearl *et al.* anticipates claim 10.

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Amending the claim to recite, “(b) the polynucleotide complementary to (a)” would overcome this rejection.

***Allowable Subject Matter***

Claim 5 is allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636